EVLASER MEDICAL DIVISION

ALBA 355

Laser Device

MEDICAL DEVICE

USER'S MANUAL

Rev. 1.0 date 20/02/12

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Appendix 1 – Technical description
Appendix 2 - Labelling

Package content

This package contains following items:

1 Laser device
2 Protection glasses
1 Pen for touch-screen use
1 Footswitch
1 Emergency button
2 Fuses
1 Feeding cable
1 User's Manual

For EU countries:
- Instructions leaflet for WEEE disposal

WARNING

IT IS FORBIDDEN TO USE PARTS OR ACCESSORIES DIFFERENT FROM THE ONES SPECIFIED IN THIS USER'S MANUAL.

0. CLASSIFICATION

Alba 355 is a medical device subject to regulations that may be different according to the country where it is marketed.

The identification label applied on the back side of the machine shows the information of the equipment that can change according to the country where the product is sold; the reproduction of this label is included in Annex 1 to this manual.

It is forbidden to remove the label; in case, for accidental reasons the label is damaged, removed, or the manufacturer's name is removed from it, the customer must notify the company Elettronica Valseriana which will provide for the restoration.

Europe

In countries belonging to the European Union - and in other countries that recognize the validity of European Directives - the Directive applied is 93/42 - Medical Devices.

With reference to this document, Alba 355 is considered a Class IIb device pursuant to Rule 9, as it is intended to release or exchange energy potentially dangerous.

For products delivered in the countries listed above:
• identification label includes information regarding the electrical characteristics expected
• includes information regarding the CE Marking
• the product is accompanied by the "Declaration of conformity" required by the Directive

1. PRESENTATION

General indications

This manual is intended to help using the medical device in a correct and informed way, for good performances and in maximum safety. To this scope any operator using, regulating and maintaining the device MUST necessarily know the information presented in this manual.

Conventions

WARNING

WARNING MESSAGES INDICATE THAT FAILURE TO FOLLOW DIRECTIONS COULD RESULT IN SEVERE DAMAGES TO PERSONS AND PROPERTIES.

WARNING

IT IS PROHIBITED USING CONTROLS, SETTINGS OR OPERATIONAL PROCEDURES DIFFERENT FROM THE ONES DESCRIBED IN THIS MANUAL.

WARNING

THIS MANUAL HAS BEEN REALIZED TO SHOW OPERATORS HOW TO USE THE DEVICE.
SOME FEATURES DESCRIBED IN THIS MANUAL MAY VARY ACCORDING TO DEVICE VERSION.
DO NOT USE THE DEVICE BEFORE READING AND UNDERSTANDING THIS MANUAL.

☝ **NOTE:** NOTES ARE PARTICULARLY IMPORTANT IN COMPARISON TO THE REST OF THE TEXT.

Manufacturer data

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How to command further copies

You can purchase further copies of this manual from the manufacturer:

2. SAFETY

Safety integration principles

The device presented in this manual has been designed and produced to be safe; each device is tested to verify conformity to EN 60601-1 standard for medical devices (or the equivalent local standard).
Elettronica Valseriana is not responsible for any damage to persons or objects caused by improper use of the product or by failure to follow safety directions.
These devices can be operated solely by trained and qualified personnel, aware of potential dangers.
This applies also for maintenance activities, which must be carried out only by highly qualified technicians, authorized by the manufacturer.
To use **ALBA 355** follow the instructions illustrated in this manual, which must be carefully read and be always available to the operator. Any use different from what shown in this manual is not recommended as it can be dangerous to persons and objects. We suggest you always contact Elettronica Valseriana for explanations or additional information.

WARNING

TO AVOID ELECTRICAL HAZARD, THESE EQUIPMENT MUST ALWAYS BE CONNECTED TO MAINS EQUIPPED WITH PROTECTIVE EARTHING.

WARNING

DO NOT REMOVE, SKIP OR MODIFY ANY COVERING OR SAFETY DEVICE.
ANY CLEANING, REGULATION, REPAIR OR LUBRICATION MUST BE CARRIED OUT WHEN THE EQUIPMENT HAS BEEN DISCONNECTED FROM MAINS FOR AT LEAST 10 MINUTES.

SAFETY SYMBOLS

	Follow use instruction CEI EN 60601-1
	Applied Part BF CEI EN 60601-1
	Protection ground wire CEI EN 60601-1

Electromagnetic Interferences

The installation place electromagnetic conditions shall not be different from the parameters set out in the tables in Annex 1 to this manual.

3. DESCRIPTION

ALBA 355 unit is a high-technology equipment for therapeutic applications in aesthetic medicine.
This manual, which must be carefully read, describes the device functionality and controls, important information regarding maintenance and indications relevant for a safe use.

General information

This manual refers to the device ALBA 355.
This manual contains a description of the controls of the device, information important for the maintenance and indications relevant for a safe use.
It is recommended that all future users of ALBA 355 read carefully the entire manual before starting any treatment.
This is an homologated device that uses a class IV laser; it is used for the treatment of lesions of the epidermal differentiation.

The laser

The laser system consists of a Neodymium source : YVO4 pumping diode. The power laser beam visible through the pointing beam, is transmitted to the treated part by a scanning head. The scan head is the "transportation mean" of YVO4 laser energy from the source to the treated area and allows to concentrate the energy in one place. The point in which the laser energy is concentrated is called the spot. The spot diameter is adjustable. The laser power YVO4 is pulsed, has a wavelength of 355 nm (UVA) and has features adjustable by the operator. The laser pointing instead is not adjustable and has a wavelength of 635 nm (visible).

Functioning

Laser is the acronym for Light Amplification by Stimulated Emission of Radiation.
The generated laser beams (power beam and pointing beam) present in the laser system are harmful to the eyesight, especially if pointed directly to the eyes.
For the use of ALBA 355 the laser beam Nd: YVO4 is concentrated on the patient in a focal point, so it is always necessary to protect yourself with the glasses provided and to avoid anyway to direct the handpiece to the eyes.

Controls panel

The controls panel (touch screen graphic display), placed in front of the unit, contains all the controls and information the operator needs to adjust the operating parameters.
The controls panel consists of a colour monitor, which includes a touch-screen functionality.
This control / visualization system make s available all controls necessary to manage device functionalities. To manage the functions of the device you just have to press the buttons on the control panel (see picture 1).

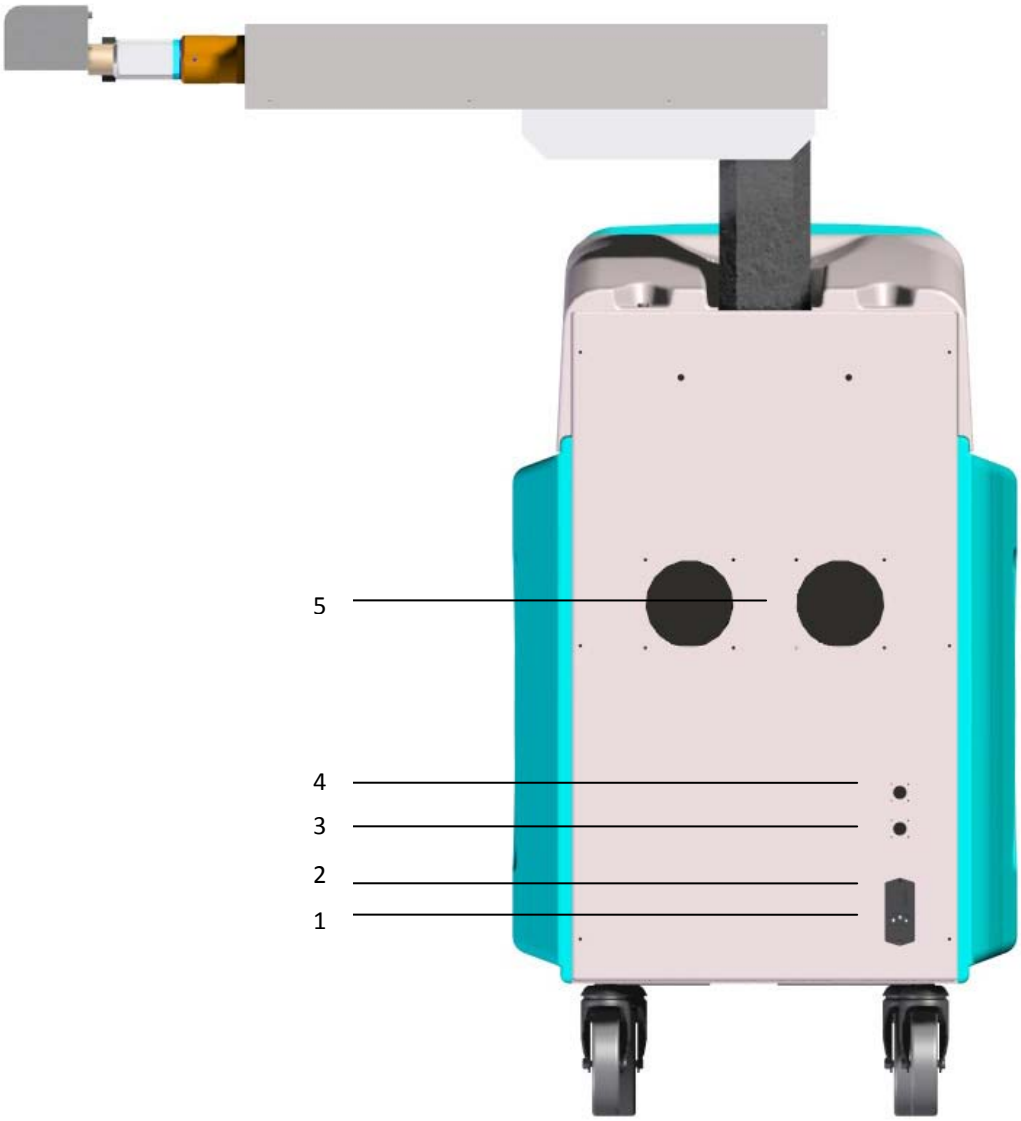
Front view

Picture 1- Device description - front

Legend

1 Castor
2 Castor brake
3 General controls panels
4 Control panel
5 Telescopic column
6 Laser source
7 Laser scan head

Rear view

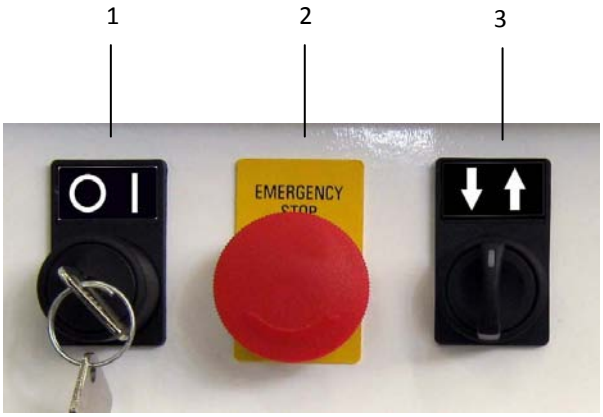


Picture 2- Device description: rear

Legend

1 Electric socket
2 Fuses
3 Footswitch socket
4 Interlock
5 Fans

General controls panel



Picture 3- General control panel

Legend

1 Key switch – to activate the laser power supply
2 Emergency button
3 Telescopic column movement selector

Key switch – to activate the laser power supply
Allows to start the power feeding section of the laser source.

Emergency button
To use only in case of emergency. If pushed it interrupts immediately the power sections of the machine.

Selector up/down
Selector used to move the telescopic column, it is usually in central position "neutral".
Turning clockwise "up", the telescopic column will extend while turning counter-clockwise "down" the column will retract. The selection will be kept until you keep the selector turned. If you leave the selector it will go back to its original position autonomously and will interrupt the movement of the telescopic column.

Control panel

Picture 4- Control panel

Legend

1 Touch-screen monitor
2 USB connector (for service)
3 Red warning light to indicate laser emission
4 White warning light to indicate the laser is ready

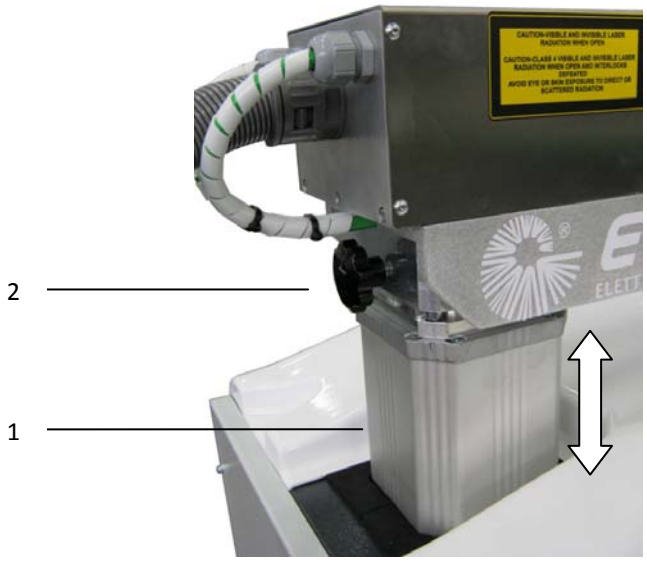
Touch screen monitor
Through this you can manage all using parameters by selecting with a touch the requested options and parameters.

USB socket (for service)
This socket is reserved solely to assistance staff.

Red warning light "Laser emission"
When active it indicates the laser output from the scanning head.

White warning light " Laser ready"
It indicates the laser is ready for emission, after turning on the key on the general controls panel.

Telescopic column



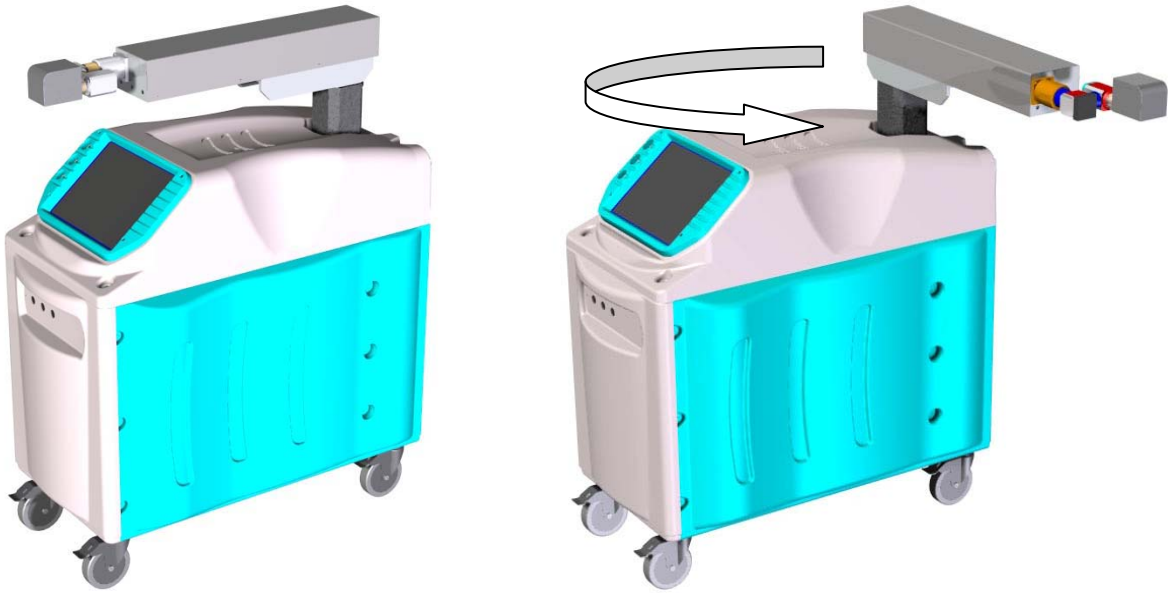
Picture 5- Telescopic column

Legend

1 Locking knob
2 Telescopic column

Locking Knob

The locking knob is used during the installation phase of the equipment for the positioning of the source group – laser scanning head, allowing to block it in the working position. To allow the movement slightly loosen the locking knob, place the source block - scanning head and then close the locking knob. The allowed movement is 90 ° as shown in the following picture.



Picture 6- Source group movement – head

Telescopic column

Allows handling on vertical axis of the source group - scanning head through the manipulation of the up / down selector placed on the general control panel.
The movement of the column is necessary in order to obtain the correct focal distance between the laser output of the scanning head and the patient. Normally the focal length is 300mm.

WARNING

THE TELESCOPIC COLUMN IS A BODY IN MOTION AND, AS SUCH, REQUIRES MAXIMUM CAUTION DURING HANDLING.
SPECIAL ATTENTION MUST BE GIVEN TO THE DANGER OF CRASHING

- BETWEEN THE LASER SOURCE AND THE TOP OF THE MACHINE FOR THE USER
- BETWEEN THE LASER SOURCE AND SCANNING HEAD FOR THE PATIENT.

WARNING

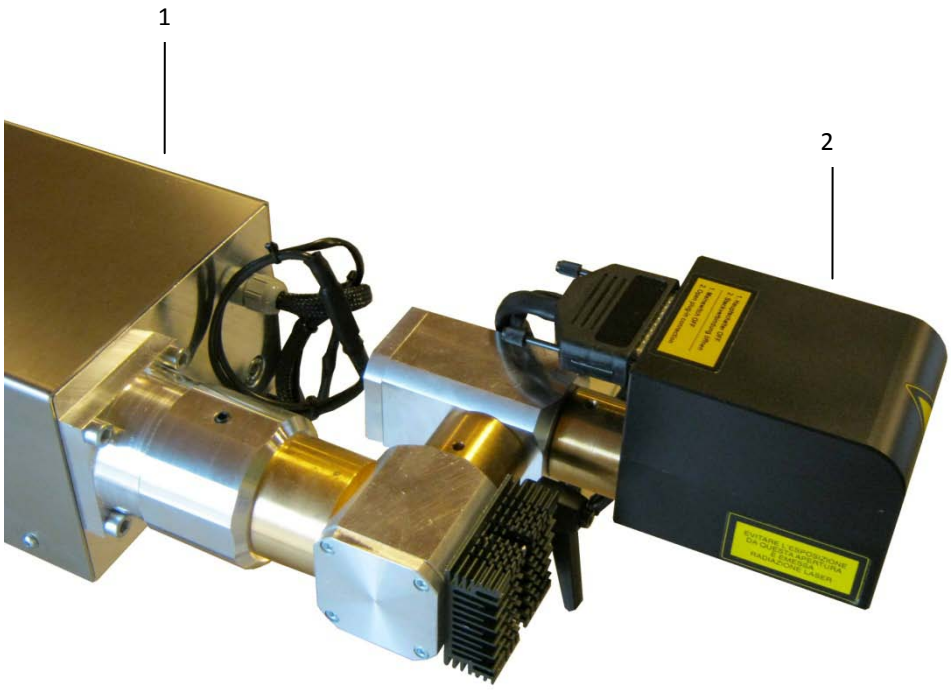
DO NOT EXERCISE MECHANICAL STRESS ON THE SOURCE GROUP / HEAD:

- THROUGH MANUAL ACTION (PRESSURE / TRACTION)
- HANGING OR PUTTING WEIGHTS.

WARNING

AVOID ANY CONTACT WITH THE INNER TERMINAL PART OF THE SOURCE GROUP.

Source Group - laser scanning head



Picture 7- Scanning head group

Legend

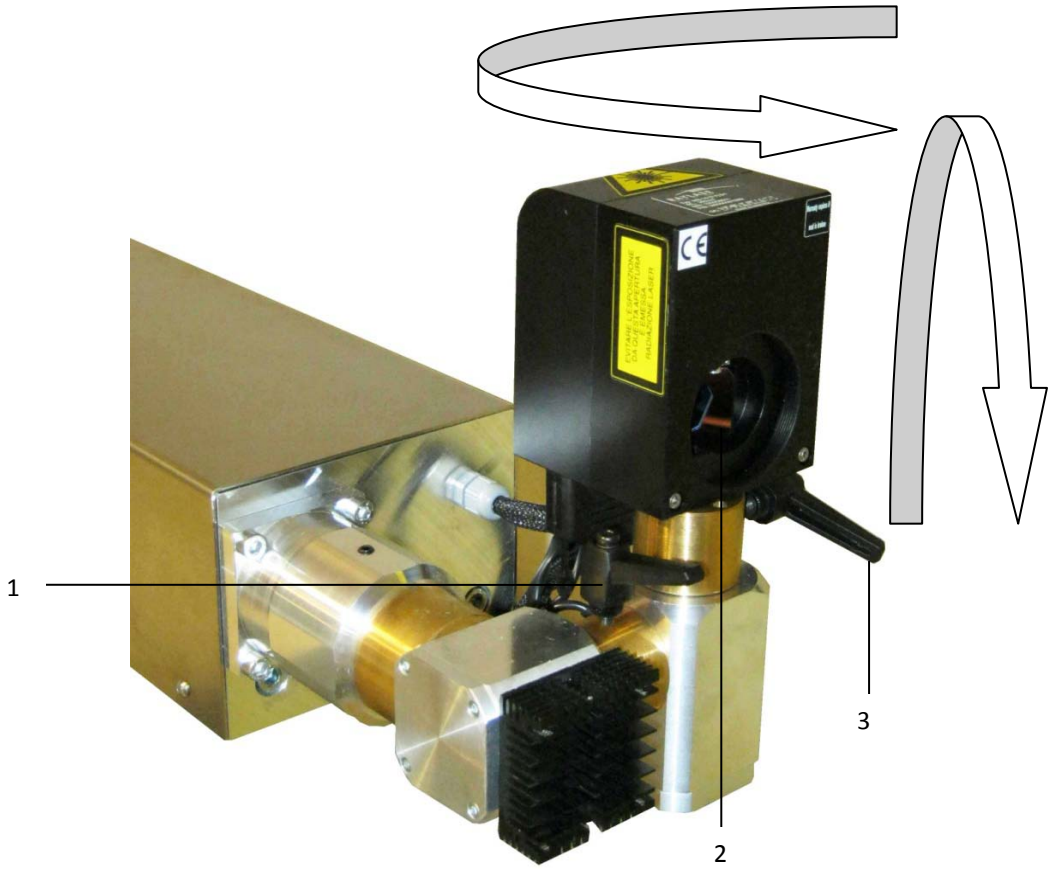
3 Laser Source
4 Laser scanning head

Laser Source
Section containing the components for the generation of the laser beam.

Laser scanning head
Connected directly to the laser source concentrates and moves the laser beam on the patient.

WARNING
EXERCISE EXTREME CAUTION WHEN HANDLING THE SOURCE GROUP - LASER SCANNING HEAD, AVOID DIRECT AND INDIRECT IMPACTS TO AVOID DAMAGE / FAILURE OF LASER DEVICES.

WARNING
IT'S FORBIDDEN TO OPEN THE PROTECTIONS ON THE LASER SOURCE AND ON THE LASER SCANNING HEAD.



Picture 8- scanning laser head -movement

Legend

1 Movement handle
2 Laser exit
3 Movement handle

Movement Handles

Through the movement handles it is possible to adjust the position (inclination - rotation) of the scanning head in order to properly address the laser beam over the treatment area of the patient.

Laser exit

Laser beam exit point.

WARNING

NEVER POINT THE LASER BEAM COMING OUT FROM THE SCANNING HEAD IN THE DIRECTION OF EYES OF PEOPLE OR ANIMALS AND FLAMMABLE OR REFLECTIVE SURFACES, IT IS COMPULSORY FOR THE OPERATOR AND THE PATIENT THE USE OF SAFETY GOGGLES PROVIDED.

WARNING

EXERCISE EXTREME CAUTION WHEN HANDLING THE SCANNING HEAD, DUE TO CRASHING DANGER FOR THE PATIENT.

4. POSITIONING AND STARTING UP

Positioning procedure and start up

The forecast installation site is hospital or a doctor's studio.
ALBA 355 must be positioned on a flat surface that allows secure placement of the equipment
Verify that the site conditions comply with those indicated in the tables

- TECHNICAL CHARACTERISTICS
- EMC ENVIRONMENTY CHARACTERISTICS

of Annex 1.

5. FUNCTIONING

Refer to the following procedures for proper use of equipment:

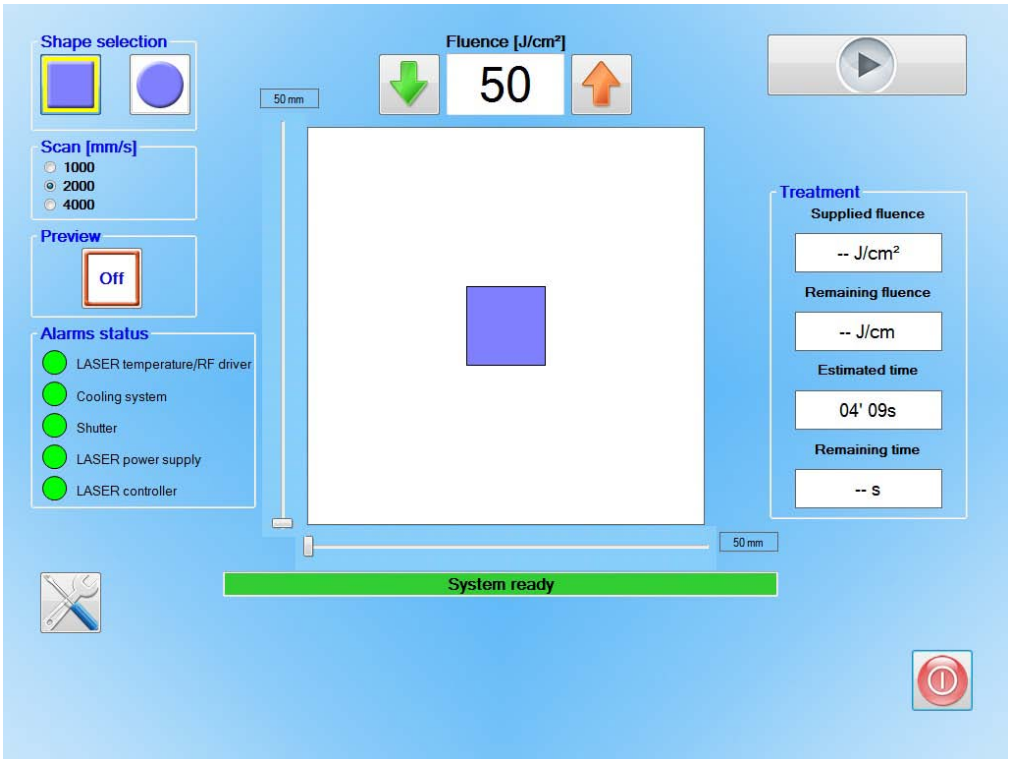
• Read this entire instruction manual and ascertain that the installation was correctly performed.

• Check that all persons within the site where the equipment is installed wear safety goggles

• Verify that the switch on the back of the machine is in position O, then connect the power cord to the mains supply.

• Place the main power switch on the back of the machine in position I.

• Turn the ignition key to start the power section of the laser; the light of white color "Laser Ready", placed on the front of the machine, indicates the laser ready status. Simultaneously the control panel will activate and – at the end of management software loading - the following screenshot will be displayed:

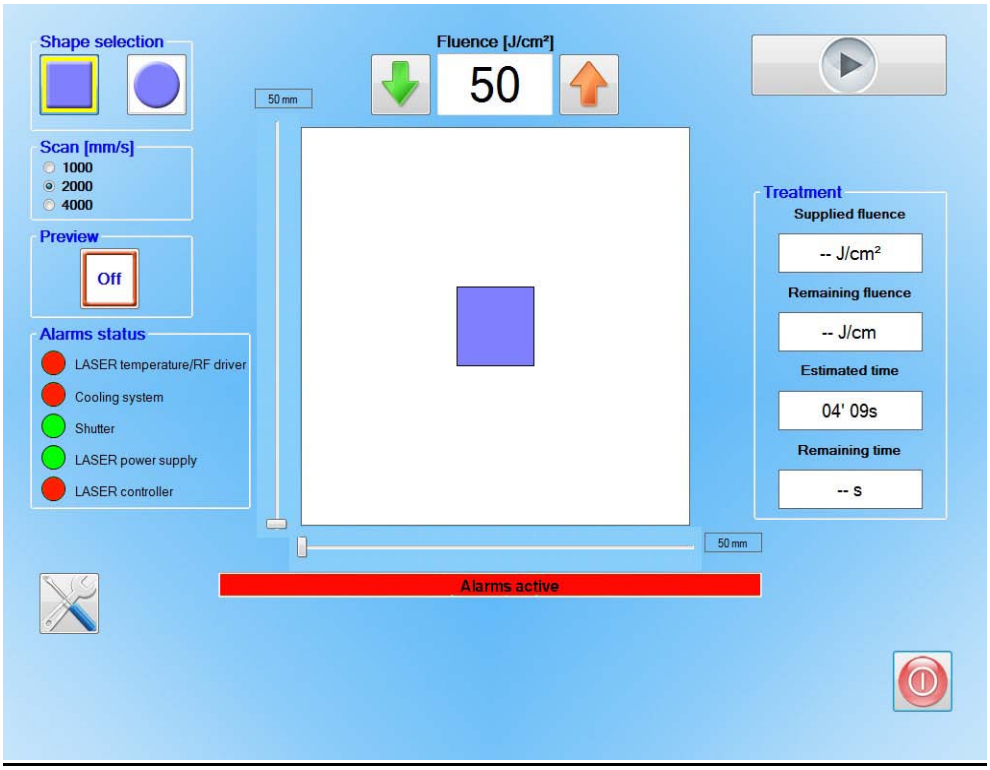


WARNING

IN THE EVENT OF EMERGENCY PRESS THE RED BUTTON ON THE FRONT OF THE EQUIPMENT.

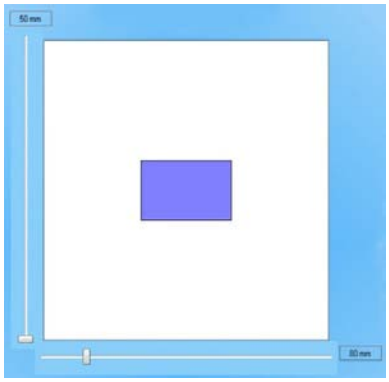
If at the switch-on the following screenshot appears, verify the key switch of the laser power is on.

For a description of the anomalies refer to paragraph "anomalies".

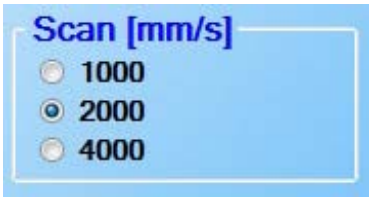


- By pressing on the control panel, select the desired shape of the scanning laser - using the "Selection form" mask. The shapes available are round or square.

- Manually dimension the selected form using the scroll bars; dimensions - in millimeters - are displayed in boxes on the side of the scroll bars



- Select the scan speed through the mask "Speed mm / s" by pressing the desired value



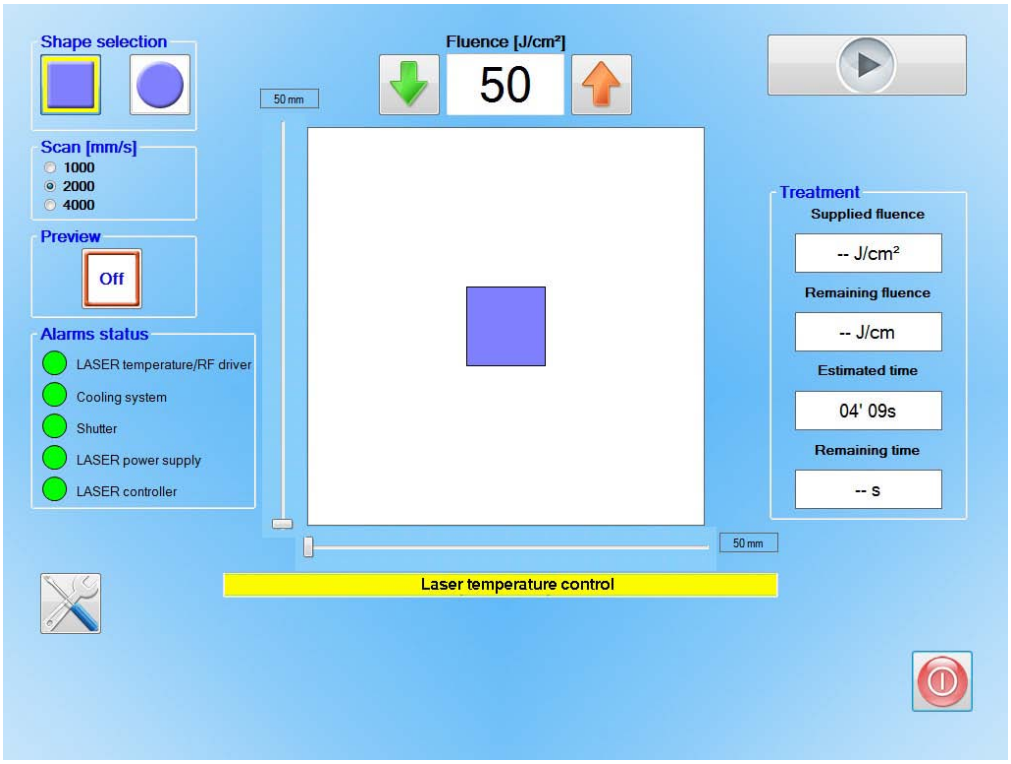
- Select Fluence from the mask “Total Requested Fluence" using the arrow keys
  - "↓" to decrease
  - "↑" to increase

  the value, in steps of 10J/cm ² from a minimum of 20J/cm ² to a maximum of 250J/cm ²
  Pressing on the numeric value indicated in the mask, a numeric keypad will appear, giving the possibility to directly set this value.

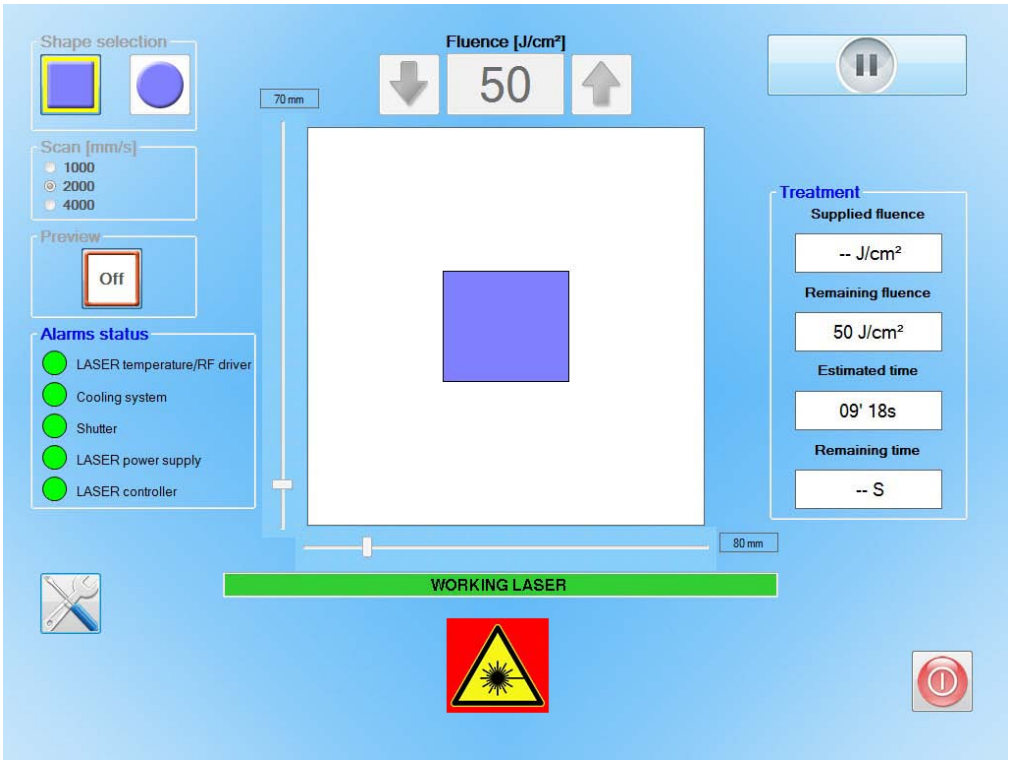
- Press the "Preview" to see directly on the patient - through the red laser pointer - the treatment area that has shape and size characteristics as previously selected.
  It’s possible to disable the preview by pressing the button again; the active state is highlighted by the word "Preview On" and the button turning yellow.

- Position the head of scanning laser at a focal distance of about 300mm from the treatment area.
- Start the treatment by pressing the "Start" button or by pressing the pedal External start.

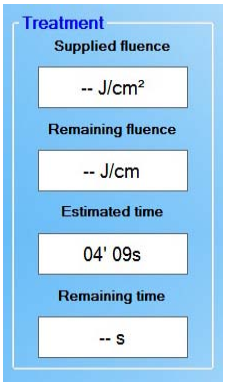
- In the main screen the status bar will indicate in yellow color " Laser Temperature Control ..." independently verifying the temperature of the laser source; the system will also test the laser power output without emission.



- Once the temperature and laser emission test is finished, the system will emit laser radiation towards the patient. On the screen this state is shown by an highlighted green bar with "WORKING LASER" writing and by the laser emission symbol at the bottom; also the red warning light aside the screen is on.



- After previous setting of the parameters, the system will show the values of fluence and timing in the mask “treatment” ; these data are calculated automatically by the software.



Supplied fluence

It shows the value of fluence delivered during the treatment.

Remaining fluence

It shows the remaining fluence to the end of the treatment.

Estimated time

It shows the estimated duration of the treatment.

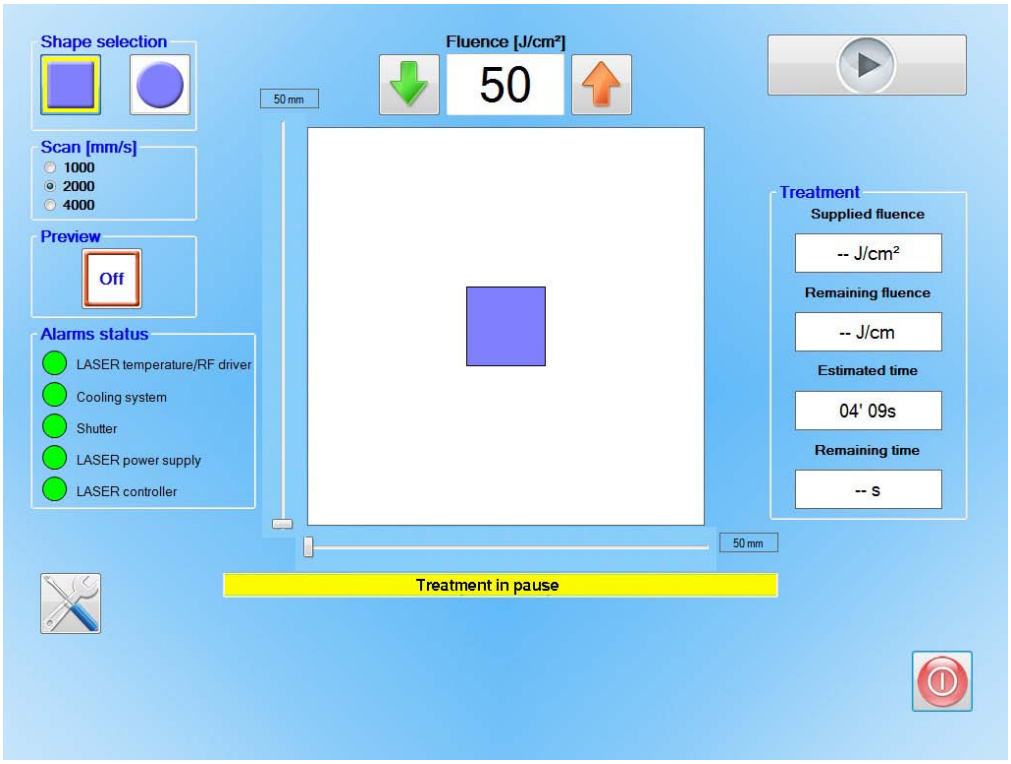
Remaining time

It shows the remaining time of the treatment.

- While working it is possible to pause or stop the treatment by pressing the following buttons:

It’s possible to pause the treatment while working also by pressing the start footswitch.

- On the screen you will see “Treatment in pause” highlighted in yellow.



- To restart the treatment press “pause” again. Before restarting the treatment the system will check the temperature and power of the laser.

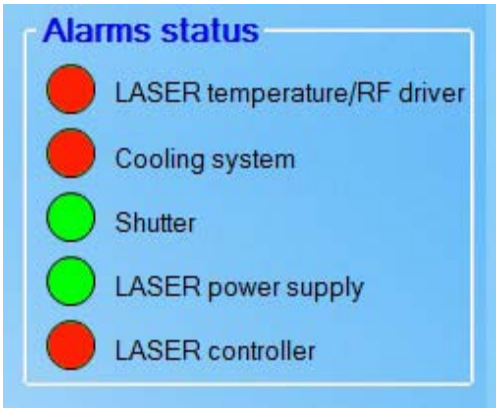
- Once the treatment is completed, turn counter-clockwise the key to “OFF” position and press “Switch off” icon on the screen.

The system will autonomously switch off.

Put the general switch in the rear of the machine in position “O” and disconnect the feeding cable.

Anomalies

If during the normal functioning there are anomalies, the device turns automatically to stand- by and you will see an alarm on the screen. Once the anomaly is solved, the alarm disappears and you can go on working normally.
You can see all possible alarms in the dedicated screenshot “Alarms”, which shows a list of Alarms next to a red or green dot, according to the state: it is red when alarm is active, green if not active.



ALARM CODE	DESCRIPTION	SOLUTION
1	Temperature / RF driver	Contact Service
2	Cooling system	Verify that the grids of the cooling fans placed on the external structure of the machine are free
		Contact Service
3	Shutter	Contact Service
4	Laser power supply	Contact Service
5	Laser controller	Verify that key switch is ON Contact Service

Alarm “Stage RF driver Temperature”
Within the laser section there is a modulator stage commanding the operation of the laser source. In case of malfunction of the modulator and / or when an abnormal temperature is reached - different from the temperature range set by the manufacturer - the system goes in to alarm. The active alarm automatically switches the device to stand-by mode. The laser emission is possible only when the alarm is not active.

Alarm “Cooling system”

During normal operation, the system ALBA 355 is constantly cooled by an autonomous internal refrigeration system. The refrigeration system is continuously monitored by suitable sensors. If for any reason the temperature deviates from the parameters set by the manufacturer, the alarm is displayed, automatically switching the unit to stand-by mode. The laser emission is possible only when the alarm is not active.

Alarm “Shutter”

Within the source of ALBA 355, there is an electromechanical device able to avoid accidental laser emission. This safety device is called "Shutter". The alarm is displayed when the shutter safety device is not working properly. The active alarm causes the automatic switching of the apparatus to stand-by mode. The laser emission is possible only when the alarm is not active.

Alarm “Power supply”

The unit contains a power supply system of the laser source.
The power supply is enabled every time the ignition key on the front panel of the device is turned ON and is disabled by placing the key in the OFF position.
In good working conditions, the power feeder switches on after 30 seconds about. If after placing the key in the ON position, the power feeder is not on, there is a fault and the alarm is displayed.
The active alarm causes the automatic switching of the apparatus to stand-by mode. The laser emission is possible only when the alarm is not active.

Alarm “Laser controller”

The unit contains a laser controller system of the source.
The laser controller is enabled every time is enabled every time the ignition key on the front panel of the device is turned ON and is disabled by placing the key in the OFF position. If after placing the key in the ON position, the laser controller is not on, there is a fault and the alarm is displayed.
The active alarm causes the automatic switching of the apparatus in stand-by mode. The laser emission is possible only when the alarm is not active.

6. THE TREATMENT

The use of ALBA 355 for the treatment of diseases must be evaluated carefully by the doctor, who must determine adequacy of treatment and working parameters (see section 7); to better understand the mechanism of action read the information written below.

Preparation of the patient

The patient must be given protective goggles (UV 355nm) which are supplied with the machine, then take a seat as per the normal treatment sessions.

The treatment

During the use of a laser you must adopt the normal procedure controls of the treatment. The operator must periodically check the progress of treatment. During the treatment, the first thing to remember is to maintain the scanning head of the laser at the correct focal distance, and as much as possible perpendicular to the surface to be treated. Then, press the footswitch to activate the laser Nd: YVO4. Pay attention to the position and to derma conditions. Like traditional procedures, the control of the results of the treatment is performed without is by visual inspection.

Warnings

Skin exposure to laser

The exposure of the skin in some cases may generate a small edema. In order to avoid this drawback, the laser scanning head must be maintained perpendicular to the surface to treat. You should also use the minimum energy, since using too much energy increases the possibility of generating excessive heat on the skin.

Patient's reaction

If a patient feels pain during the treatment one possible cause is the accumulation of heat, generated by the irradiation. This heat spreads to the nerve endings and may damage them, even irreversibly. In this case the operator should pause the treatment and cool down the area. If restarting the treatment the patient feels pain again you will need to stop the treatment.

Precautions

If the patient suffers from one of the following malfunctions and takes specific medicines he must inform the operator prior to any intervention:

Allergies	Arthritis
Asthma	Depression
Diabetes	Epilepsy
Immunodeficiency	Hypertension
Hyperthyroidism	Heart diseases

We advise you to avoid any kind of treatment during pregnancy, not because harmful to the fetus, but for the particular hormonal status of women during gestation.

Aim

The emissions generated for the treatment interact with the tissues that make up the derma. Part of the emission, however, is reflected from the surface of the derma, therefore, the most efficient mode of application is the one through where light power hits the tissue with an angle of about 90 °.

Patient movement
In order to prevent irradiation of tissues different from the ones to treat, the patient must stay as much still as possible .

Energy used
During treatments always use the minimum energy so to reduce the risk of damages to the treated areas.

Procedures

The unit ALBA 355 is indicated for the treatment of lesions due to the epidermal differentiation on most of the human body. To avoid that the emission reaches the retina while passing through the tissues, it is recommended not to treat areas near the eyes.

WARNING

THE CONTINUE REPETITION OF LASER PULSES IN ONE AREA MAY BURN THE PATIENT.

WARNING

MOVEMENTS OF THE PATIENT MUST NOT COMPROMISE THE SAFETY OF THE TREATMENT. IF YOU CANNOT DO THE TREATMENT SAFELY INTERRUPT IMMEDIATELY.

WARNING

START LASER EMISSION ONLY WHEN THE SCANNING HEAD OF THE LASER IS DIRECTED TOWARDS THE AREA TO TREAT.

WARNING

NEVER POINT THE LASER SCANNING HEAD TOWARDS THE EYES OF PEOPLE OR ANIMALS OR TOWARDS FLAMMABLE OR REFLECTIVE SURFACES. THE OPERATOR AND THE PATIENT MUST USE THE GOOGGLES SUPPLIED WITH THE DEVICE.

WARNING

THE INTENSITY OF THE POWER USED DURING A TREATMENT CHANGES FROM A SURFACE TO ANOTHER. EACH TREATMENT MUST START WITH THE MINIMUM ENERGY. INCREASE THE INTENSITY OF POWER APPLIED TO SURFACE SUBJECT TO TREATMENT ONLY IF IT IS STRICTLY NECESSARY.

7. USING PROTOCOLS

Introduction

Artificial rays (UVA) such as sunbeds, lamps, solar panels, are used both in the beauty and medical field, obviously for different applications. Besides broadband emission, narrowband UVA has recently been introduced in the market: UVB (311 nm band – TL01), UVA2 (320-340 nm) and UVA1 (340-400nm). These wavelengths allow to get therapeutic advantages in the treatment of psoriasis, vitiligo (UVB 311nm) and atopic dermatitis (UVA1). Further to these pathologies - where results are consolidated - selected band phototherapy is being studied for other types of dermatosis. In principle an evaluation of the quantity of energy deliverable on the skin lets us identify an initial dose of: 0,2- 0,4 J cm2 (UVB narrowband) and 1,2-1,5 J cm2 for UVA or UVA1.

UVA1 action mechanism

Unlike UVB and UVA2 (315-340nm) the biological effects of UVA1 are obtained through aerobic photo-oxidation reactions, with the intermediate formation of reactive species of oxygen, such as singlet oxygen, superoxide anion and hydroxyl radicals. The anaerobic formation of photo-products between tymines is completely unimportant. In Caucasians about the 37% of emitted UVA1 penetrates the skin until 60-90 µm, therefore these wavelengths can effectively modulate the immunological and inflammatory activities of cellular populations resident not only in the epidermis but also in the derma. On Keratinocytes UVA1 induces the synthesis and the release of IL-6, IL-8, IL-10 (with consequent reduction of IL-12 and interferon-g), a-MSH (with reduction of IL-1 and TNF-a) and PGE2 (with inhibition of the activation of lymphoid cells Th1) and inhibits the expression of ICAM-1.5.
Unlike UVB and UVA2, UVA1 can induce the apoptosis of lymphoid cells T, in particular T helper, non only through delayed mechanisms, which depend on a synthesis “de novo” of some proteins, but even through precocious mechanisms, pre-programmed and independent from protein synthesis.
UVA1 provokes the production of PGE2 and thromboxanes in the Langerhans cells, but doesn’t affect their number and functionalities and does not induce their migration into satellite lymph nodes.
Finally, UVA1 can affect the activity of fibroblasts with increase of the synthesis of collagenases 1 and a reworking on the stroma with an increase in the urinary excretion of the waste products of collagen I and III.

Therapy protocols

The protocols for the photo-therapy UVA1 entail the irradiation of low (6.5-20J/cm2), medium (40-60J/cm2) or high dosages (100-130J/cm2) with no need to increase dosages during the therapy.

Cumulative doses for low dosages are estimated lower than 300J/cm2, those for medium dosages are included between 300 and 975J/cm2 and for high dosages between 975 and 1840J/cm2. 1,2,3,4

Usually non coherent UVA1 emitters have lighting radiations in a spectrum included between 340 and 400nm, but sometimes we can find radiations higher than 530nm and other infrared radiations have been isolated (780-300 nm). With monochromatic radiation, the wavelength of UVA1 is 355nm.

Clinical indications

Atopic dermatitis

In controlled studies, short cycles with UVA1 with medium or high doses proved to be more effective than combined photo-therapy UVAB and topic application of steroids.

With low doses we obtain lower therapeutic results. To a clinic improvement we associate the reduction of the number of eosinophils both circulating and infiltrating skin and the reduction of the number and functionality of lymphoid cells T helper on damaged skin.

The number and the structure of the Langerhans cells do not change, instead.

The expression of ICAM-1 on the Keratinocytes of the lesion reduces, but the plasmatic levels of circulating ICAM-1 don't show variations. The plasmatic levels of Eosinophil Cationic Protein (ECP) reduce, while the results of the studies of modifications of other serum parameters, like sCD23, mastocytosis tryptase, IFN-g and total lgE are conflicting.

Mycosis fungoides

High doses of UVA1 proved to be effective in the treatment of mycosis fungoides both in the initial phase of spots or plaques and in advanced shapes such as nodular or erythrodermic lesions.

The therapeutic action is most likely obtained by the activation of apoptosis mechanisms of malignant T cells infiltrating epidermis and derma.

Lupus erythematosus

Low doses of UVA1 can reduce the entity of some clinical appearance of systemic and subacute lupus erythematosus, like cutaneous lesions, arthralgia, morning muscular rigidity, asthenia, fever.

Such clinical improvement accompanies the increase of the number of leucocytes and the reduction of antibodies anti-nucleus and anti-ENA.

The therapeutic action is most likely obtained by the induction of apoptosis of T lymphoid cells infiltrating the skin and, in Keratinocytes, by the promotion of DNA reparation, by the interference and translocation of nuclear soluble antigens non-histone like the SSA/Ro and by the reduction of IL-12 levels.

Scleroderma

High dosed of UVA1 have been successfully used in the therapy of morphea both in adults and in children, in acrosclerosis and cutaneous effects of systemic sclerosis.

Lesions show reduction of the derma thickness with reduction of collagen fibers and an increase of elastic fibers. The therapeutic action can be referred both to the reduction of the number of T lymphoid cells infiltrating the plaques and to the increase of collagen activity of the fibroblasts.

Psoriasis

In skin treated with psoralenes, the maximum photo-toxic and anti-psoriasic activity is obtained with wavelengths included between 320 and 330 nm.

Two types of UVA sources are widely used for PUVA-therapy. Fluorescent UVA lamps emission pick is 352nm and emit about 0,5% in the UVB band. The emission of filtrated halogen-metallic lamps contains more UVA1 and UVB (1,5%-3,0%), higher irradiance, and a better space homogeneity of the emission.

In the light of what written in literature we wanted to introduce a therapeutic protocol based on the same energetic intensities of UVA but without the aid of chemotherapy drugs.

In the therapy of psoriasis we therefore used high energy frequencies in weekly sessions that brought to a progressive remission of the therapy. We believe the effectiveness of this therapy comes from the demonstrated capability to reduce the proliferation of T lympho cells and the production of cytokines (both Th1 and Th2).

Vitiligo

We have done photo-therapies - without the aid of chemotherapy drugs - in medium doses with biweekly frequency. The treated lesions did not exceed the 25% of the total body surface and we excluded peripheral areas.

The treatment with UVA rays with wavelength included between 320-400 nm (UVA) would be able to induce skin pigmentation, even if the action mechanism is partially unknown. A radiation in the UVA1 spectrum stimulates the proliferation and the migration of melanocytes from the hair follicle and from the margins of the lesion, the production of melanin, through the formation of photo-adduced with DNA and the induction of an inflammatory reaction.

Protocols resuming table

	J/cm2 (single)	J (cumulative)	Sessions per week
ATOPIC DERMATITIS	**20**	**1000**	**3**
MYCOSIS FUNGOIDES	**130**	**2000**	**2**
LUPUS ERYTHEMATOSUS	**6**	**250**	**2**
SCLERODERMA	**100**	**1500**	**2**
SCLEROATROPHIC LICHEN	**100**	**1000**	**2**
PSORIASIS	**130**	**1800**	**3**
VITILIGO	**100**	**1500**	**3**

Side effects

Negative short-term effects are rare and limited to the occasional appearance of a modest and reversible xerosis with pruritus and possible intensification of a pre-existing photo-dermatosis.

We didn't observe long-term side effects on men, but studies on murine models do not permit to exclude potential carcinogen and an action promoting photo- ageing.

Visible laser beam

In unit ALBA 355 the invisible Nd: YVO4 beam is parallel to a visible solid status beam. This one (red) is used to ensure the operator points the scanning head on the right area to treat. The beam must be as much as possible perpendicular to the surface to treat. In case you cannot see the laser beam after pressing START or its intensity is reduced, there could be damage due to an improper use of the laser or of the scanning head.

8. CLEANING, DISINFECTION

Wipe the unit Periodically with a soft sponge soaked with a solution of mild soap. Avoid creating streams that can penetrate inside the machine. Dry with a soft cloth. Clean the cord, taking care to dry all the plugs and connectors. When not used, store the device in a dry dust-free place, not outside. During periods of long disuse keep the machine disconnected from the power.
Do not put any heavy equipment or liquids above the machine. To work properly over the years, an annual review is needed.
It 'a good idea to clean the handpiece using solutions for local antisepsis type Barrycidal.
It is also necessary to clean the screen using a micro fiber cloth so that controls are always visible.

WARNING

BEFORE DOING ANY MAINTENACE OPERATION, DISCONNECT THE EQUIPMENT FROM THE ELECTRIC FEEDING.

9. MAINTENANCE

WARNING

ANY ELECTRONIC, MECHANIC OR ELECTRIC OPERATION MUST BE DONE BY AUTORISED AND SPECIALISED PERSONNEL.

WARNING

BEFORE DOING ANY MAINTENACE OPERATION, DISCONNECT THE EQUIPMENT FROM THE ELECTRIC FEEDING.

There is no maintenance by the user, except for cleaning and disinfection as described in paragraph 8 above; it is responsibility of the operator (or organization responsible) the periodic review of:

- The general integrity of the unit, the integrity and readability of labels and markings applied to the unit.
- Integrity status of the feeding cable.

In case of any signal of malfunctioning (like excessive heating, strange noises, etc..) :

- Stop working immediately
- Call the assistance service

The following maintencance operations are expected to be done periodically (every 12 months) by the technical assistance staff:

- Power control calibration
- Power control
- Calibrations control
- General control of electrical, electronic and mechanic components.

In some countries regulations state specific checks on electrical equipment every two years; these must always be done by the technical assistance of the manufacturer.